

MAY 23 2001

K011324 p.1/4

## 510(k) Summary

April 30, 2001

**Submitter:** Cambridge Heart, Inc  
1 Oak Park  
Bedford, Ma 01730  
(781) 271-1200  
(781) 275-8431

**Contact:** Dave Chazanovitz

### 510(k) Numbers and Product Codes of equivalent devices:

Cambridge Heart, Inc.; Alternans Processing System

510(k) Number: #K003492

Product Code: 74 DQK

CFR Section: 870.2340

Cambridge Heart, Inc.; Model CH 2000 Cardiac Diagnostic System

510(k) Number: #K983102

Product Code: 74 DPS

CFR Section: 870.2340

### Indications for Use and Intended Population

The Model CH 2000 Cardiac Diagnostic System is intended for the recording of electrocardiograms, vector cardiograms and measurement of Microvolt T-Wave Alternans\* at rest and during ECG stress testing.

The presence of Microvolt T-wave Alternans as measured by the analytic spectral method of the Model CH 2000 Cardiac Diagnostic System in patients with known, suspected or at risk of ventricular tachyarrhythmia predicts increased risk of a cardiac event (ventricular tachyarrhythmia or sudden death).

The Model CH 2000 Cardiac Diagnostic System should be used only as an adjunct to clinical history and the results of other non-invasive and/or invasive tests.

The predictive value of T-wave Alternans for cardiac events has not been established in patients with active, untreated ischemia.

\*Microvolt T-wave Alternans is defined as T-wave alternans which (a) is measured from high-resolution multi-segment sensors, (b) is present in leads X, Y, Z, VM or two adjacent precordial leads, (c) is at the level of 1.9 microvolts after signal optimization and subtraction of the background noise level, (d) is at least three standard deviations greater than the background noise level, (e) has an onset heart rate at or below 110 beats per minute, and (f) is sustained for all heart rates above the onset heart rate.

**Device Description**

The Cambridge Heart CH 2000 Cardiac Diagnostic System is a computer based ECG system which includes the optional feature for the measurement and recording of T-Wave alternans.

The CH 2000 Cardiac Diagnostic System simultaneously records and stores a standard 12 lead or 15 lead ECG; a selection of 3, 6, or 12 channels are displayed in real time. ECG recordings may be output to the printer or stored on optical disk. The CH 2000 Cardiac Diagnostic System controls resting and exercise stages of stress tests conducted according to Bruce, modified Bruce, Naughton, Sub-Maximal and Astrand protocols. The Physician may also customize a protocol according to his or her preference.

The CH 2000 cardiac Diagnostic System computes measurements of ST segment slope and level continuously during testing, and displays selected real time 3, 6, or 12 lead (operator selected) ECG traces as well as 12 median beat recordings with optional superimposed median resting beat for reference. The CH 2000 also computes, ST integral, ST index, and alternating beat to beat T-wave amplitude (alternans) for up to 15 leads during exercise stress testing. All ECG data are provided for evaluation and interpretation by a qualified physician; the CH 2000 does not offer interpretations of the recordings nor suggests possible diagnoses.

The Alternans test is performed with seven standard stress test electrodes and seven proprietary multi-segment Hi-Res™ or Micro-V™ sensors. The electrodes and sensors are attached through a leadwire set to the belt-worn PM-3, which provides digitized data to the CH 2000.

**Patient Electrodes:**

Patient electrodes designed and approved specifically for use during exercise stress testing should be used at all times with the Cambridge Heart Model CH 2000 Cardiac Diagnostic System.

Measurement of alternating beat to beat T-wave amplitude (alternans) requires the use of the Cambridge Heart Hi-Res Electrode (Ref: # K962115) or The Cambridge Heart Micro-V Alternans Sensor (Ref: #K002230) in conjunction with other Patient electrodes designed and approved specifically for use during exercise stress testing.

**Standard Hardware Components**

<b>System Cart:</b>	Mounts Computer, display, keyboard, and output devices. Dimensions assembled (approximate); 58 x 25.5 x 26 in.
<b>Computer and Keyboard:</b>	IBM compatible, including hard disk floppy disk and interface cards.
<b>Display:</b>	15 inch color monitor on swivel tilt bracket.
<b>ECG Amplifier</b>	The ECG Amplifier is embodied in the PM-3, (PM-2 optional) patient module. 12 leads/10 electrodes. Plugs into computer.
<b>Printer:</b>	Windows © compatible printers, Strip Chart Recorder.
<b>Serial Treadmill Interface:</b>	Standard RS-232 interface allows computer control of speed and incline. (Requires optional RS-232 interface cable.)
<b>Serial Bicycle Interface:</b>	Analog interface allows computer control of resistance and measurement of RPM for Lode Corival ergometer. (requires optional analog cable).
<b>Software:</b>	System and diagnostic software is provided on floppy disk.
<b>Shipping Containers:</b>	Cart, Computer and Display are shipped in a single container.

**Standard Hardware Accessories**

<b>Patient Cable:</b>	Set of 10 or 14 lead wires which meet the requirements of 21CFR 898.12 and comply with IEC-601-1; 56.3c part 1.1, General Requirements for Safety  Individual patient leads are either not detachable, or user detachable with female socket connections such that no conductive surface is exposed when unconnected.
<b>User Manuals:</b>	Operators manual supplied standard with every system. Service manual supplied upon request. Physicians Guide to T-Wave Alternans processing supplied with T-wave Alternans Option. T-wave alternans Course Training Manual supplied in conjunction with training course.

**Performance Standards**

The Cambridge Heart Model CH 2000 Cardiac Diagnostic System meets the following Performance Standards:

ANSI/AAMI EC11-1991

EN60601-1: 1988, "Medical Electrical Equipment, Part 1: General Requirements for Safety" including Amendments A1 and A2

EN60601-1-1: 1993, "Medical Electrical Equipment, Part 1: General Requirements for Safety - Section 1.1 Collateral standard: Safety requirements for medical electrical systems"

EN60601-1-2: 1993, "Medical Electrical Equipment, Part 2: Collateral Standard: Electromagnetic Compatibility – Requirements and Tests"

UL2601-1, "Medical Electrical Equipment, Part 1: General Requirements for Safety" 2<sup>nd</sup> Edition, including Amendments A1 and A2

CAN/CSA C22.2 No. 601.1-M90, "Medical Electrical Equipment, Part 1: General Requirements for Safety" including C22.2 No. 601.1S1-94 (IEC 601-1, Amendment 1:1991)

**Conclusion**

There are more similarities than differences between the predicate device and the Cambridge Heart Model CH 2000 Cardiac Diagnostic System. Both the predicate devices use the Analytic Spectral Method of Alternans Processing. When used in accordance with the directions for use, by qualified personnel, the Cambridge Heart Model CH 2000 Cardiac Diagnostic System is safe and effective, as indicated, for its intended use.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 23 2001

Cambridge Heart, Inc.  
c/o Mr. John D. Greenbaum  
Generic Devices Consulting  
20310 SW 48<sup>th</sup> Street  
Ft. Lauderdale, FL 33332

Re: K011324  
Trade/Device Name: Model CH 2000 Cardiac Diagnostic System  
Regulation Number: 870.1425  
Regulatory Class: II (two)  
Product Code: 74 DQK  
Dated: April 30, 2001  
Received: May 1, 2001

Dear Mr. Greenbaum:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

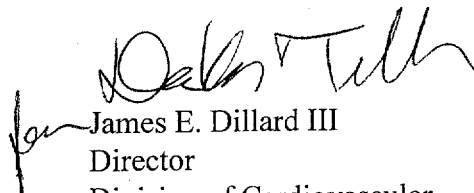
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

  
James E. Dillard III  
Director  
Division of Cardiovascular  
and Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number(if known): K011324

Device Name: Model CH 2000 Cardiac Diagnostic System

Indications For Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use     

(Optional Format 1-2-96)

  
Division of Cardiovascular & Respiratory Devices  
510(k) Number K011324